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EXAMINER	
DOUGHERTY, SEAN PATRICK	
ART UNIT	**PAPER NUMBER**
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,519	DUDA ET AL.	
	Examiner	Art Unit	
	SEAN P. DOUGHERTY	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/10/2007, 08/06/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is the *initial* Office action based on the 10/553519 application filed August 1, 2006. Claims 26-49, as amended, are currently pending and have been considered below. Claim 26 is independent.

Claim Objections

Claims 26-49 are objected to because of the following informalities:

Claims 26, 27, 32, 33, 36, 37, 38, 39 and 42 recite the limitation "the individual musculoskeletal strains";

Claims 26 and 30 recite the limitation the limitation "the varied musculoskeletal parameters".

There is insufficient antecedent basis for this limitation in these claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 26, the limitation "musculoskeletal reference strains corresponding to the musculoskeletal reference parameters are determined as the individual musculoskeletal strains" in claim 1, it is unclear the relationship between the musculoskeletal reference strains and the individual musculoskeletal.

Examiner is unsure if the individual musculoskeletal strains are determined by the same method as the musculoskeletal reference strains, if the individual musculoskeletal strains are the same value as the musculoskeletal reference strains or if the individual musculoskeletal strains are the same strains as the musculoskeletal reference strains.

Regarding claim 31, part e. of claim 26 does not recite variation of the individual musculoskeletal parameters, rather the variation of at least one musculoskeletal parameter.

For examination purposes the variation of the individual musculoskeletal parameters has been interpreted as varying the variation of at least one musculoskeletal parameter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26, 27, 31-38 and 40-49 are rejected under 35 U.S.C. 102(b) as being anticipated by DiGioia, III et al (US Patent No. 6,205,411: cited in IDS).

Regarding claim 26, DiGioia discloses a method for simulating musculoskeletal strains on a patient for monitoring surgical interventions (col. 7, lines 64-67), the method comprising the steps of:

a. determining individual musculoskeletal parameters of the patient (col. 6, lines 49-67) and automatically deriving anthropometric parameters from a system for computer-assisted surgery (col. 7, lines 1-10);

b. automatically determining the individual musculoskeletal strains from the determined musculoskeletal parameters of the patient (col. 7, lines 11-18); and

c. for the automatic determination of the individual musculoskeletal strains, comparing the individual and varied musculoskeletal parameters with musculoskeletal reference parameters filed in a strain database constructed with empirical data (col. 7, lines 19-33; col. 7, lines 48-50), and musculoskeletal reference strains corresponding to the musculoskeletal reference parameters are determined as the individual musculoskeletal strains (*see 112 second paragraph rejection*; col. 7, lines 19-33), the musculoskeletal reference parameters being present as discrete values in the strain database (col. 5, line 67 to col. 6, lines 5; col. 6, lines 9-12; col. 7, lines 36-40; col. 7, lines 54-57) and the musculoskeletal reference parameters being compared with the

individual musculoskeletal parameters by means of functional relationships (col. 7, lines 46-63); and

d. evaluating the individual musculoskeletal strains in respect of at least one target criterion (col. 7, lines 27-29).

Regarding claim 27, DiGioia discloses the method as claimed in claim 26, further comprising the steps of:

e. varying at least one musculoskeletal parameter (col. 7, lines 34-36);

f. subsequently automatically determining the individual musculoskeletal strains taking into consideration the at least one varied musculoskeletal parameter (col. 7, lines 19-33); and

g. subsequently evaluating the individual musculoskeletal strains in respect of the at least one target criterion (col. 7, lines 48-50).

Regarding claim 31, DiGioia discloses the method as claimed in claim 27, wherein:

the variation of the individual musculoskeletal parameters in step e. is carried out taking into consideration predefinable data for implants (*see 112 second paragraph rejection;* col. 7, lines 27-33).

Regarding claim 32, DiGioia discloses the method as claimed in claim 26, wherein:

the individual musculoskeletal strains are calculated from the determined individual musculoskeletal parameters (col. 7, lines 15-18).

Regarding claim 33, DiGioia discloses the method as claimed in claim 32, wherein:

a biomechanical and/or a mathematical model is used as a basis for the calculation of the individual musculoskeletal strains (col. 7, lines 19-22).

Regarding claim 34, DiGioia discloses the method as claimed in claim 33, wherein

the biomechanical and/or mathematical model is adapted to the individual musculoskeletal parameters (col. 7, lines 22-26).

Regarding claim 35, DiGioia discloses the method as claimed in claim 33, wherein:

the biomechanical and/or mathematical model is chosen on the basis of the determined individual musculoskeletal parameters from at least one database (col. 7, lines 27-45).

Regarding claim 36, DiGioia discloses the method as claimed in claim 34, wherein:

the individual musculoskeletal strains are calculated with the aid of a musculoskeletal model taking into consideration the individual patient anatomy (col. 7, lines 11-18).

Regarding claim 37, DiGioia discloses the method as claimed in claim 26, wherein:

the individual musculoskeletal strains are visualized for evaluation (col. 6, lines 17-21).

Regarding claim 38, DiGioia discloses the method as claimed in claim 26, wherein:

the individual musculoskeletal strains are presented on the basis of an anatomical model, particularly in graph form and/or numerically (col. 6, lines 50-61; col. 7, lines 11-22).

Regarding claim 40, DiGioia discloses the method as claimed in claim 26, wherein:

the individual musculoskeletal parameters of the patient are determined by measurements (col. 6, lines 50-54).

Regarding claim 41, DiGioia discloses the method as claimed in claim 40, wherein:

at least one of the individual musculoskeletal parameters is measured automatically (col. 6, lines 55-58).

Regarding claim 42, DiGioia discloses the method as claimed in claim 26, wherein:

individual movement parameters, particularly gait parameters, are determined (col. 7, lines 19-33), and these are used for the automatic determination of individual musculoskeletal strains (col. 7, lines 46-63).

Regarding claim 43, DiGioia discloses the method as claimed in claim 42, wherein:

the individual gait parameters are determined from personal data stored in a database and/or are recorded individually for one person (col. 7, lines 48-63).

Regarding claim 44, DiGioia discloses the method as claimed in claim 26, wherein:

the position and/or orientation of joints are used for a navigation system for computer-assisted surgery and/or the data from a navigation system are used for computer-assisted surgery (col. 6, lines 24-48).

Regarding claim 45, DiGioia discloses a device for evaluating musculoskeletal strains on a patient, with means for carrying out the method as claimed in claim 26 (apparatus, 10).

Regarding claim 46, DiGioia discloses a movement analysis system coupled to the device as claimed in claim 45 (col. 6, lines 24-48).

Regarding claim 47, DiGioia discloses a navigation system for computer-assisted surgery for carrying out the method as claimed in claim 26 (col. 6, lines 24-48).

Regarding claim 48, DiGioia discloses a method as claimed in claim 26, wherein:

the musculoskeletal parameters are automatically measured anthropometric parameters (col. 7, lines 1-10).

Regarding claim 49, DiGioia discloses a method as claimed in claim 26, wherein:

the target criterion include contact forces, degree of joint movement, fragment movements of a fracture or any combination thereof (col. 7, lines 46-50).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over DiGioia, III et al (US Patent No. 6,205,411: cited in IDS).

Regarding claim 28, DiGioia discloses the method as claimed in claim 27, wherein:

a specific target value of at least one target criterion is reached.

DiGioia does not appear to explicitly disclose wherein:

step e. to g. are repeated until a specified target value of at least one target criterion is reached.

However, it would have been obvious to one of ordinary skill in the art to repeat the steps e. to g. until a specified target value of at least one target criterion is reached as this process is inherent as disclosed by DiGioia. DiGioia establishes the variation of size and orientations of implant components along with the variation of test positions (col. 7, lines 34-36) and simulating various conditions to calculate a range of motion for each condition (col. 7, lines 46-48), comparing each value to a predetermined range of motion to determine an optimized calculated range (col. 7, lines 48-53). It is inherent from the disclosure of DiGioia that steps e. to g. are repeated as this would be done to determine the calculated range from each of the simulations of various conditions to determined the optimized range.

Regarding claim 29, DiGioia discloses the method as claimed in claim 28, wherein:

the musculoskeletal parameters corresponding to the target value are output on an output unit, stored in a storage unit and/or transferred to a computer-assisted surgery system and/or to a surgical navigation system (col. 6, lines 24-48).

Regarding claim 30, DiGioia discloses the method as claimed in claim 28, wherein:

the individual and varied musculoskeletal parameters corresponding to the target value serve as a basis for planning a surgical intervention, the positioning of

components or the decision regarding the removal of temporary implants (col. 6, lines 24-48).

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over DiGioia, III et al (US Patent No. 6,205,411: cited in IDS) in view of Wham et al (US Publication No. 2005/0203504).

Regarding claim 39, DiGioia discloses the method as claimed in claim 26, wherein:

by evaluation of the individual musculoskeletal strains, a rehabilitation process is evaluated and/or managed (col. 6, lines 21-23)

DiGioia does not appear to disclose the method as claimed in claim 26, wherein:

by evaluation of the individual musculoskeletal strains, a rehabilitation process is evaluated and/or managed, particularly by means of Internet access.

However, Wham, a reference in analogous art discloses the method as claimed in claim 26, wherein:

by evaluation of the individual musculoskeletal strains, a rehabilitation process is evaluated and/or managed, particularly by means of Internet access (¶0061).

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of DiGioia and Wham before him or her to modify the evaluation and/or managing of the rehabilitation process of DiGioia to be evaluated and/or managed by means of Internet access of Wham. The motivation for doing so would have been to include instrument operating information, mappings, diagnostic information, algorithms or programs which are updated on a regular basis and downloaded to the generator as needed during surgery (Wham: ¶0061) which can be performed remotely from the surgical theater (DiGioia: col. 6, lines 21-23).

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN P. DOUGHERTY whose telephone number is (571)270-5044. The examiner can normally be reached on Monday-Thursday, 7:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. P. D./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736